

Applicants' Remarks

Claims 1-28 are pending. Applicants thank the Examiner for indicating that claims 17, 22, and 23 are allowable.

Restriction and Rejoinder

Claims 9-11, 14-16, 18-21 and 24-28 are withdrawn. Applicants respectfully disagree with the reason provided in the Office action for finalizing the restriction requirement. In particular, Applicants respectfully direct the Examiner's attention to M.P.E.P. § 821.04 (withdrawn claims that contain all the limitations of the allowed claim are eligible for rejoinder) for rejoinder of Group II, and M.P.E.P. § 821.04(b) (withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder) for rejoinder of the claims in Group III. In view of these requirements, Applicants again request rejoinder of withdrawn claims.

In particular, in view of the acknowledged allowability of claim 17, claims 18-21 must be rejoined and examined herein (as claims that depend from and include all the limitations of an allowable claim). Similarly, in view of the acknowledged allowability of claim 22, claims 24, 25, and 26 must be rejoined and examined in the current application (as process claims that depend from and include all the limitations of an allowable product claim). It is believed that these currently-withdrawn claims are allowable.

Rejection under 35 U.S.C. § 102(b):

Claims 1, 2, 8, 12, and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hanke *et al.* (WO 01/47955). Applicants respectfully traverse.

The claims are directed to an isolated recombinant polyepitope polypeptide comprising, *inter alia*, amino acid segments that comprise epitopes selected to be at least 50% sequence conserved across a plurality of HIV-1 subtypes. According to the Office, Hanke *et al.* teach polypeptides comprising CTL epitopes and that these epitopes are conserved sequences across HIV clades. While Hanke *et al.* list a number of CTL epitopes, the reference does not teach one of skill in the art to select only those epitopes that are at least 50% sequence conserved across a plurality of HIV-1 subtypes. The

only selection criteria listed by Hanke *et al.* is that the CTL epitope be recognized by at least 0.01% of the world's human population (see Hanke *et al.*, page 7, first full paragraph). Therefore, one of skill in the art would have no reason to select epitopes that are at least 50% sequence conserved across a plurality of HIV-1 subtypes. The Office has provided no indication that the CTL epitopes selected by the method of Hanke *et al.* would inherently result in the same set of epitopes that would have been obtained by the selection criterion in claims 1, 2, 8, 12, and 13.

Applicants respectfully submit that Hanke *et al.* do not disclose, either explicitly or inherently, all the limitations of claims 1, 2, 8, 12, and 13. Therefore Hanke *et al.* does not and cannot anticipate these claims and Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. § 103(a):

Claims 3-7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hanke *et al.* as applied to claims 1, 2, 8, 12, and 13 in view of Velders *et al.* (*J. Immunol.* 166:5366-5373, 2001), Lopalco (U.S. Pat. Appl. Pub. No. 2003/0003440), and Carbone *et al.* (*J. Immunol.* 138(6):1838-1844, 1987). Applicants respectfully traverse.

As indicated above, Hanke *et al.* does not teach selection of only those epitopes that are at least 50% sequence conserved across a plurality of HIV-1 subtypes. Further, there is no suggestion in Hanke *et al.* that one of ordinary skill in the art select only those epitopes that are at least 50% sequence conserved across a plurality of HIV-1 subtypes. Indeed, one would not be motivated to select epitopes by this method because Hanke *et al.* already provide a different selection criterion. Velders *et al.*, Lopalco, and Carbone *et al.* do not overcome the deficiencies of Hanke *et al.* Therefore, claims 3-7 are not unpatentable over Hanke *et al.* in view of Lopalco, and Carbone *et al.* and Applicants respectfully request withdrawal of this rejection.

Claims 1-8, 12, and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Woodberry *et al.* (*J. Virol.* 73(7):5320-5325, 1999) in view of Suhrbier (*Expert Rev. Vaccines* 1(2):207-213, 2002), Velders *et al.*, Lopalco, and Carbone *et al.* Applicants respectfully traverse.

Woodberry *et al.* do not teach or suggest to one of ordinary skill in the art selection of only those epitopes that are at least 50% sequence conserved across a plurality of HIV-1 subtypes. As explained in footnote “a” on page 5321, Woodberry *et al.* select their epitopes from those described by Brander and Walker and Dupuis *et al.* (*J. Immunol.* 155(4):2232-2239, 1995). As indicated in the Office Action, Brander and Walker list known HIV CTL epitopes (over 900). There is, however, no reason for one of skill in the art to select from this list only those epitopes that are at least 50% sequence conserved across a plurality of HIV-1 subtypes. The epitopes selected by Dupuis *et al.* had demonstrated binding affinity for HLA-A 0201 (see Abstract of Dupuis *et al.*). In other words, the epitope selection methods of Brander and Walker nor Dupuis *et al.* are different from those claimed and the Office has provided no reason why one of skill in the art would deviate from the epitope selection methods of Brander and Walker or Dupuis *et al.*, and particularly not how one of skill in the art would reach Applicants’ invention based on the teachings of these references.

None of Suhrbier, Velders *et al.*, Lopalco, and Carbone *et al.* overcome the deficiencies of Woodberry *et al.* Therefore, Applicants respectfully submit that claims 1-8, 12, and 13 are not unpatentable over Woodberry *et al.* in view of Suhrbier, Velders *et al.*, Lopalco, and Carbone *et al.* and respectfully request withdrawal of this rejection.

Conclusion

Applicants believe that the claims are in condition for allowance. The Examiner is encouraged to contact the undersigned by telephone if any clarification is desired.

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